UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,505	01/09/2006	Joerg Rosenberg	M/43212-US-1	4705

26474 7590 01/07/2009
NOVAK DRUCE DELUCA + QUIGG LLP
1300 EYE STREET NW
SUITE 1000 WEST TOWER
WASHINGTON, DC 20005

EXAMINER	
KATAKAM, SUDHAKAR	

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
01/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,505	ROSENBERG ET AL.	
	Examiner	Art Unit	
	Sudhakar Katakam	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the application

1. Receipt of Applicant's request for continued examination filed on 7th Oct 2008 is acknowledged.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed 7th Oct 2008 has been entered.

2. Claims 23-37 are examined on the merits in this office action.

Claim Rejections - 35 USC § 102

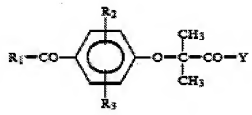
3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by **Boyer** (US 4,800,079).

Boyer discloses a medicine based on fenofibrate, and a method of preparing it. **Boyer** defined the term "fenofibrate and its derivatives" to designate a compound having the formula I, is represented by the following formula:



The above formula reads instant claim 1 when R_1 is phenyl group, R_2 and R_3 are hydrogen atoms, and Y is a -OH group [col. 1, lines 10-31]. **Boyer also** discloses binders selected from the group comprising methacrylic polymers, polyvinylpyrolidone, mixtures thereof; cellulose derivatives and polyethylene glycols [see claim 2].

Therefore, the claim 1 is fully met with the above formula and binders disclosed by **Boyer**.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

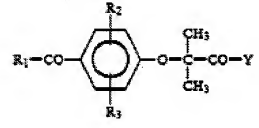
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 23-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over by **Boyer et al** (US 4,800,079), in view of **Kothrade et al** (US 6,284,803).

Boyer teaches a medicine based on fenofibrate, and a method of preparing it. **Boyer** defined the term "fenofibrate and its derivatives" to designate a compound having the formula I, is represented by the following formula:



The above formula reads instant claim 1 when R_1 is phenyl group, R_2 and R_3 are hydrogen atoms, and Y is a -OH group [col. 1, lines 10-31]. **Boyer also** teaches various binders, selected from the group comprising methacrylic polymers, polyvinylpyrolidone, mixtures thereof; cellulose derivatives and polyethylene glycols [see claim 2].

Boyer et al is deficient in that the dependent limitations in claims 24-37 are not explicitly stated in the composition. However, **Kothrade et al** cure this deficiency.

Kothrade et al teach a pharmaceutical formulation [col. 14, line 45] in dosage form [col. 1, line 4] comprising fenofibrate as the active ingredient [col. 7, line 39], in the form of a molecular dispersion [col. 10, line 48], and a polymeric binder composed of methy/methacrylate, acrylic acid, cellulose acetate phthalate and hydroxypropylmethylcellulose phthalate [col. 5, lines 11-13, 20-21] and other

conventionally acceptable excipients [col. 1, lines 4-7], which include flow regulators and silicates/silica gel [col. 6, lines 1 and 12]. The formulation is further obtainable by melt extrusion [col. 2, line 8; col. 5, line 35]. The formulation has a ratio of free carboxyl groups to esterified carboxyl groups around 1:1, based on the weight percentage of methyl methacrylate to acrylic acid [col. 2, lines 56-61] and the use of Eudragit types, which Applicant uses to exemplify this ratio preference [col. 5, line 12; col. 10, line 39] [see also specification page 7, lines 3-10]. The formulation comprises 0.1 to 95%, preferably from 20 to 80%, in particular 30 to 70% by weight of the active substance [col. 6, lines 61-63], with ranges of 15-83% for the binder [col. 2, lines 19-45], in which the enteric binder (Eudragit types) is in the preferable range of up to 75% by weight of the binder component [col. 4, lines 65-67; col. 5, line 1 and 12] and with the range of up to 100%, in particular 0.02-50% of pharmaceutically/physiologically acceptable additives [col. 5, lines 66-67; col. 6, lines 7-8]. The preceding percentages would include a formulation in which the content of active substance component relative to binder is from 20 to 30% by weight.

Kothrade et al further teaches that all three components of the formulation: fenofibrate, binder component and other excipients/additives, can be combined [col. 1, lines 4-7; col. 7, lines 10-12 and 39].

In reference to claim 37, which describes a method for oral administration, it is the position of the examiner that since the dosage is in tablet form [col. 10, line 67], the expected mode of administration is orally. Additionally, Applicant states that fenofibrate is usually administered orally [specification page 1, line 15].

In reference to claim 25 and 26 which describes the binder as an enteric binder/enteric polymer, because the art describes the polymeric binder with the same components as Applicant's, which include methyl methacrylate, acrylic acid, cellulose, acetate phthalate and hydroxypropylmethylcellulose phthalate [col. 5, lines 11-13, 20-21], it is the position of the Examiner that the enteric property is inherent to the binder/polymer composition.

The claims would have been obvious because, a person of ordinary skill has a good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product, not of innovation, but of ordinary skill and common sense.

The claim would have been obvious because the design incentives or market forces provided a reason to make an adaptation, and the invention resulted from application of the prior knowledge in a predictable manner.

All the claimed elements were known in the prior art and one skilled person in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to have yielded predictable results to one of ordinary skill in the art at the time of the invention.

The Supreme Court in KSR noted that if the actual application of the technique would have been beyond the skill of one of ordinary skill in the art, then the resulting

invention would have been obvious because one of ordinary skill could not have been expected to achieve it.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to combine the components of **Kothrade et al** for the formulation of **Boyer et al** to arrive at a fenofibric acid composition for pharmaceutical oral administration. The expected result would be an effective lipid-regulating tablet in dosage form.

Response to Arguments

8. Applicant's arguments filed on 7th Oct 2008 have been fully considered but they are not persuasive.

Applicants argue that **Boyer** fails to teach each and every element of the claimed invention and Kothrade et al do not disclose or suggest fenofibric acid.

However, examiner disagree with applicants remarks. **Boyer**, clearly defined the meaning of "fenofibrate and its derivatives" and also various binders for the medicine in the form of granules. The **Boyer's** formula **(I)** becomes fenofibric acid, when R_1 is phenyl group, R_2 and R_3 are hydrogen atoms, and Y is a -OH group [col. 1, lines 10-31]. Therefore it reads every element of applicants claim 1.

Kothrade et al, in an analogous process, also clearly suggested a pharmaceutical formulation [col. 14, line 45] in dosage form [col. 1, line 4] comprising fenofibrate as the active ingredient [col. 7, line 39], and a polymeric binder composed of methy/methacrylate, acrylic acid, cellulose acetate phthalate and hydroxypropylmethylcellulose phthalate. With regard to the filed declaration, applicants

show how the cited references differ from the instant invention, but the obviousness test under 35 U.S.C. 103 is whether the invention would have been obvious in view of the prior art taken as a whole. **In re Metcalf et al. 157 U.S.P.Q. 423.**

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to combine the above cited references and arrive at a fenofibric acid composition for pharmaceutical oral administration with a reasonable expectation of success. The expected result would be an effective lipid-regulating tablet in dosage form.

Conclusion

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/

Examiner, Art Unit 1621

/SHAILENDRA - KUMAR/

Primary Examiner, Art Unit 1621